IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. 1,149/4 ounce round metal tins, more or less, of an article of drug, labeled in part: (tin) "*** CHICKWEED HEALING SALVE *** Usage: Good for skin disorders *** Made by: S.A.E.G. ***," 244/2 ounce round metal tins, more or less, of an article of drug, labeled in part: (tin) "*** TO-MOR-GONE *** (Black Salve) *** Ingredients: Blood Root, ***," 316/1/3 fluid ounce glass bottles, more or less, of an article of drug, labeled in part: (bottle) "*** R.E.P. *** For sinus infection, *** Made by: S.A.E.G. ***" and all other quantities of the above articles of drug, in any size and type of container, whether labeled or unlabeled, that are located anywhere on the premises of Notions-n-Things Distribution, 20497 Hwy 65, Bogard, Missouri, and which are labeled or otherwise determined to have originated outside the state of Missouri, Defendants,	)	Civil No. 12-0362-CV-W-GAF

and)
)
Samuel A. Girod d/b/a S.A.E.G.,)
)
Claimant/Defendant.)

FIRST AMENDED COMPLAINT FOR FORFEITURE IN REM AND FOR CONDEMNATION AND PERMANENT INJUNCTION

The United States of America, by David M. Ketchmark, Acting United States Attorney for the Western District of Missouri, for its first amended complaint, states as follows:

1. This amended complaint is filed by the United States of America, and requests the condemnation and forfeiture of articles of drug, as described in the caption, in accordance with the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301 *et seq.*, 334. This amended complaint also seeks a statutory injunction, under 21 U.S.C. § 332 and the equitable authority of this court, against Samuel A. Girod d/b/a S.A.E.G., to restrain and enjoin violations of the Act.

I. FORFEITURE

2. On on March 27, 2012, Plaintiff, the United States of America, by and through its undersigned counsel, filed with the court a Verified Complaint for Forfeiture *In Rem* seeking the condemnation and forfeiture of the above-captioned articles ("Defendants *in rem*") pursuant to 21 U.S.C. § 334.

3. This court has jurisdiction over this matter pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provides federal courts with jurisdiction over seizures brought under the Act.

4. Venue is proper in this district pursuant to 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1) because the defendant property is located at Notion-n-Things Distribution, 20497 Highway 65, Bogard, Missouri.

5. Defendants *in rem* are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1), because they are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.

6. Examples of drug claims on the product label for CHICKWEED HEALING SALVE include: "Good for skin disorders. Dry skin, cuts, burns, draws, and poison ivy." Claims made for the product in promotional literature and on internet websites include: ". . . conditions, such as cough, rheumatoid arthritis, psoriasis, stomach ulcers, and as a blood cleanser."

7. Claims for TO-MORE-GONE found on the aforementioned websites include: ". . . to remove warts, moles and draw infections." "Bloodroot . . . anti-infective properties, used on warts, fungoid tumors, nasal polyps, and periodontal infections, gingivitis, and plague. With cancer, it has been shown to be most effective with carcinomas and sarcomas."

8. Drug claims found on the label for R.E.P. include: "For sinus infections." Claims found in promotional pamphlets for the product include: ". . . for stress headaches . . . ."

9. Defendants *in rem* are new drugs within the meaning of the Act, 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended or suggested in their labeling, and they may not be marketed in interstate commerce unless they are the subject of an approved new drug application. 21 U.S.C. § 355(a). There are no such approved applications or exemptions from such requirements in effect for the articles described in the caption. 21 U.S.C. §§ 355(b) or (i).

10. Defendants *in rem* are misbranded while held for sale after shipment in interstate commerce within the meaning of the Act, 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use and Defendants *in rem* are not exempt from such requirement under 21 C.F.R. §§ 201.100(c)(2) and 201.115, since Defendants *in rem* are unapproved new drugs.

11. The articles of drug CHICKWEED HEALING SALVE and TO-MOR-GONE are misbranded within the meaning of the Act, 21 U.S.C. § 352(f)(2), because they fail to bear adequate warnings about the risks of toxicity and allergic reactions in consumers who are sensitive to certain ingredients contained in the articles. The labeling for the drug CHICKWEED HEALING SALVE does not bear adequate warnings about the risks of the ingredient comfrey. Comfrey consists of pyrrolizidine alkaloids, which may increase the risk of systemic toxicity. The labeling for the drug TO-MOR-GONE does not bear adequate warnings about the risks of the ingredient bloodroot. Bloodroot is an escharotic agent, a caustic, corrosive substance that produces a thick scar that can mask tumor recurrence.

12. The articles of drug CHICKWEED HEALING SALVE and TO-MORE-GONE are further misbranded within the meaning of the Act, 21 U.S.C. § 352(j), because the articles are dangerous to health when used in the manner, frequency or duration recommended or suggested in their labeling, due to the presence of the ingredients comfrey (CHICKWEED HEALING SALVE), and bloodroot (TO-MORE-GONE).

13. The article of drug R.E.P. is also misbranded within the meaning of the Act, 21 U.S.C. § 352(e)(1)(A), because its labeling does not contain any ingredient information.

14. Pursuant to a Warrant of Arrest *in Rem* issued by this court, Dkt. 4, the United States Marshal for this District seized Defendants *in rem* on March 28, 2012, Dkt. 7.

15. On May 15, 2012, Samuel A. Girod intervened and filed a claim to the Defendants *in rem*. See Dkt. 9.

16. Wherefore, the United States requests that this court decree the condemnation of the Defendants *in rem* and forfeit all existing Defendants *in rem* to the United States and grant plaintiff the costs of this proceeding against the claimants of the Defendants *in rem*; that the remaining Defendants

in rem be disposed of as this Court may direct pursuant to the provisions of the Act; and that plaintiff obtain such other and further relief as the case may require.

II. INJUNCTIVE RELIEF

17. The United States seeks a statutory injunction under the Act, 21 U.S.C. § 332(a), and the equitable authority of this Court, to enjoin and restrain Samuel A. Girod d/b/a S.A.E.G. ("Claimant/Defendant") from: (a) violating 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(b) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i); (b) violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. §§ 352(f)(1), (f)(2), (j), and (e)(1)(A); and (c) violating 21 U.S.C. § 331(k), by misbranding within the meaning of 21 U.S.C. §§ 352(f)(1), (f)(2), (j), and (e)(1)(A) an article of drug while such drug is held for sale after shipment of one or more of its components in interstate commerce.

18. This Court has jurisdiction over this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345. Venue in this district is proper under 28 U.S.C. § 1391(b).

19. Claimant/Defendant, an individual, is the sole manufacturer of the drugs CHICKWEED HEALING SALVE, TO-MOR-GONE, and R.E.P. Claimant/Defendant manufactures these drugs in his home and barn, which are located at 409 Satterfield Lane, Owingsville, Kentucky. Claimant/Defendant is the most responsible individual, and was observed giving orders during the manufacturing of CHICKWEED HEALING SALVE.

20. Claimant/Defendant receives raw ingredients used to manufacture his drugs in interstate commerce, including beeswax from West Babylon, New York, and rosemary, eucalyptus, peppermint, mint, and lavender from Mishawaka, Indiana. Claimant/Defendant's drugs are shipped in interstate

commerce, including to customers and distributors in Cincinnati, Ohio and Bogard, Missouri, within the jurisdiction of this court.

21. As described above, Claimant/Defendant's CHICKWEED HEALING SALVE, TO-MOR-GONE, and R.E.P. are drugs within the meaning of 21 U.S.C. § 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

22. Claimant/Defendant's drugs are also new drugs within the meaning of 21 U.S.C. § 321(p) because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggesting in their labeling, and they may not, under 21 U.S.C. § 355(a), be introduced or delivered for introduction into interstate commerce unless they are the subject of an approved new drug application. No such approvals of applications filed pursuant to 21 U.S.C. §§ 355(b) or (j) or exemptions from such requirements pursuant to 21 U.S.C. § 355(i) are in effect for Claimant/Defendant's drugs. In addition, Claimant/Defendant's drugs are misbranded within the meaning of the Act, 21 U.S.C. §§ 352(f)(1), (f)(2), (j), and (e)(1)(A).

23. Claimant/Defendant has a long history of introducing and delivering for introduction into interstate commerce unapproved new drugs and misbranded drugs.

24. Most recently, the United States Food and Drug Administration ("FDA") conducted an inspection of Claimant/Defendant's manufacturing operation, located at 409 Satterfield Lane, Owingsville, Kentucky, between March 13, 2012, and March 19, 2012. Although Claimant/Defendant terminated the inspection before it was completed, FDA investigators were able to, among other things, collect samples of Claimant/Defendant's product labeling. Labeling for CHICKWEED HEALING SALVE collected during the inspection states that the product is "[g]ood for skin disorders. Dry skin, cuts, burns, draws, and poison ivy," and lists comfrey as an ingredient, which consists of pyrrolizidine alkaloids. Labeling for TO-MOR-GONE collected during the inspection lists bloodroot

as an ingredient, which is an escharotic agent. Labeling for R.E.P. collected during the inspection states that the product should be used "[f]or sinus infections . . . ."

25. Previously, FDA attempted to inspect Claimant/Defendant's manufacturing operation on January 31, 2012. FDA investigators collected samples of Claimant/Defendant's product labeling, but Claimant/Defendant refused to allow FDA investigators to inspect the manufacturing operation. Labeling for Claimant/Defendant's CHICKWEED HEALING SALVE collected during the inspection stated that the product was "[g]ood for skin disorders. Dry skin, cuts, burns, draws, and poison ivy," and listed comfrey as an ingredient, which consists of pyrrolizidine alkaloids. Labeling for Claimant/Defendant's TO-MOR-GONE collected during the inspection listed bloodroot as an ingredient, which is an escharotic agent. Labeling for Claimant/Defendant's R.E.P. collected during the inspection stated that the product should be used "[f]or sinus infections . . . ."

26. On July 16, 2010, FDA inspected a distributor of Claimant/Defendant's CHICKWEED HEALING SALVE in Madison, Indiana. During this inspection, FDA investigators photographed the labeling for Claimant/Defendant's CHICKWEED HEALING SALVE, which stated that the product was "[g]ood for skin disorders. Dry skin, cuts, burns, draws, and poison ivy," and listed comfrey as an ingredient.

27. On March 30, 2005, FDA attempted to inspect Claimant/Defendant's manufacturing operation, which was then located at 1362 Highway 129, Canaan, Indiana. Defendant relocated from Canaan, Indiana, to Owingsville, Kentucky, in 2006. Claimant/Defendant refused to allow the FDA investigator to inspect the manufacturing operation. The investigator, however, collected labeling for Claimant/Defendant's CHICKWEED HEALING SALVE from a distributor in Madison, Indiana. The labeling stated that the product was "[g]ood for skin disorders. Dry skin, cuts, burns, draws, and poison ivy," and listed comfrey as an ingredient.

28. On September 22, 2004, FDA attempted to inspect Claimant/Defendant's manufacturing operation in Canaan, Indiana. Claimant/Defendant provided the FDA investigator with labeling for CHICKWEED HEALING SALVE, but refused to allow the FDA investigator to inspect the manufacturing operation. The labeling stated that the product was "[g]ood for skin disorders. Dry skin, cuts, burns, draws, and poison ivy," and listed comfrey as an ingredient.

29. On October 2, 2003, the Ohio Department of Agriculture sent a letter to Claimant/Defendant, warning him that the labeling for CHICKWEED HEALING SALVE contained therapeutic claims, and that these claims caused the product to be a new drug under the Act.

30. On December 28, 2001, FDA inspected Claimant/Defendant's Canaan, Indiana, manufacturing operation to collect samples of Claimant/Defendant's product labeling. During this inspection, the FDA investigator collected samples of CHICKWEED HEALING SALVE's labeling, which stated that the product was "[g]ood for all skin disorders. Skin cancer, cuts, burns, draws, and poison ivy," and listed comfrey as an ingredient.

31. During each of the above-described inspections and attempted inspections of Claimant/Defendant's manufacturing operation, FDA investigators explained to Claimant/Defendant that his labeling contained drug claims, and that such claims cannot be made unless a new drug application is in effect for the product.

32. Despite FDA's efforts, Claimant/Defendant continues to manufacture and distribute his drugs and has refused to modify his labeling to eliminate drug claims.

33. Unless enjoined by this court in the manner requested, Claimant/Defendant will continue to violate the Act in the manner alleged.

34. Wherefore, the United States prays that the court:

A. Order that Claimant/Defendant, and each and all of his officers, agents,

employees, representatives, successors, assigns, and attorneys, and those persons in active concert or participation with Claimant/Defendant, be permanently restrained and enjoined pursuant to 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done all of the following acts:

i. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce any new drug, as defined by 21 U.S.C. § 321(p), that is neither approved pursuant to 21 U.S.C. §§ (b) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

ii. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. §§ 352(f)(1), (f)(2), (j), and (e)(1)(A); and

iii. Violating 21 U.S.C. § 331(k), by causing drugs that Claimant/Defendant holds for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(f)(1), (f)(2), (j), and (e)(1)(A);

B. Grant such other and further equitable relief as the Court deems just and proper; and

C. Award the United States its costs, including overhead, and such other and further equitable relief as the case may require.

Respectfully submitted,

DAVID M. KETCHMARK
Acting United States Attorney

By:

/s/ James Curt Bohling
JAMES CURT BOHLING
Assistant United States Attorney
Chief, Monetary Penalties Unit
400 E. 9th Street, Fifth Floor
Kansas City, Missouri 64106
Telephone: (816) 426-7173
E-mail: Curt.Bohling@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that on September 28, 2012, the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system.

/s/ James Curt Bohling
James C. Bohling
Assistant United States Attorney
Chief, Monetary Penalties Unit